**Mississippi Division of Medicaid**
**Drug Utilization Review (DUR) Board**
**Minutes of the May 20, 2010 Meeting**

**Members Attending:** William Bastian, M.D.; Gera Bynum, R.Ph; Alvin Dixon, R.Ph; Edgar Donahoe, M.D.; Lee Merritt, R.Ph; Mark Reed, M.D.; Paul Read, Pharm D; Jason Strong, Pharm D; Frank Wade, M.D.
**Members Absent:** Jason, Dees, D.O.; Laura Gray, M.D.; Vickie Veazey, R. Ph

**Also Present:**
**DOM Staff:** Judith Clark, R.Ph., DOM Pharmacy Bureau Director; Paige Clayton, Pharm D., DOM DUR Coordinator; Terri Kirby, R.Ph., DOM Clinical Pharmacist;
**HID Staff:** Ashleigh Holeman, Pharm D., Project Manager; Leslie Leon, Pharm D., Clinical Pharmacist; Kathleen Burns, R.N., Call Center Manager

**Call to Order:** Dr. Mark Reed, Chairman of the Board, called the meeting to order at 2:03 p.m. Dr. Reed asked for a motion to accept the minutes from the meeting of February 18, 2010. Dr. Paul Read made a motion to accept the minutes with a second from Dr. Bastian. All voted in favor of the motion.

Dr. Reed continued the meeting by moving into the cost management analysis under the direction of Dr. Holeman.

**Cost Management Analysis:**
Dr. Holeman began the presentation with the Top 15 Therapeutic Classes by total cost of claims dating December 2009 thru February 2010. This report remains constant with Antipsychotic Agents leading the top therapeutic classes. The Top 25 Drugs based on the number of claims for these same dates remains consistent with hydrocodone-acetaminophen, azithromycin and amoxicillin as the highest utilized medications through the Mississippi Medicaid pharmacy benefit. The Top 25 Drugs based on total claims costs report varied slightly with Singulair®, Abilify® and Synagis® in the top three positions for the time period analyzed.

**Pharmacy Program Update:**
Ms. Clark began by noting several upcoming changes with the DOM pharmacy program. The newest PDL will be introduced on July 1, 2010 with several changes. It was noted that on the alphabetical hand-out to the Board that the preferred Brands were listed with notations of highlighted additions and deletions from the preferred list. This was made available to providers throughout the state by DOM to alert them of the upcoming pharmacy program changes. Ms. Clark also noted several generics that would no longer be preferred which might cause some confusion for providers. These changes were carefully scrutinized by DOM to manage the costs to the program without compromising the care of the beneficiary. She continued that there would not be “grandfathering” for the PPI therapeutic class or the short-acting beta-agonist inhalers. Dr. Reed questioned the reason for Prevacid® Solutabs as preferred products as opposed to the Prevacid® capsules or the generic equilivent product. Ms. Clark reminded the Board that the

majority of the Medicaid beneficiaries are now under the age of 21. Prevacid® Solutabs met the needs of this age group. In the therapeutic class of growth hormones, Ms. Clark stated that there would be a consideration for stable therapy. If the beneficiary has been non- compliant with the non-preferred agent, they will be required to restart treatment with a preferred agent. The antiemetic agent ondansetron will be open for all beneficiaries, with the oral tablets being the preferred formulation. The only carve-out would be for beneficiaries under age 11, for whom the ondansetron ODT will be approved. This medication will still have the set quantity limits of 12 tablets/units per 30 days. Once again, Ms Clark reminded the Board that DOM does cover the acne products for beneficiaries under age 21. The confusion at the pharmacy point of sale is that not all generics are covered. This then causes more confusion to the physician when he receives a call from the pharmacist to submit a prior authorization. Ms.Clark referred the Board to the PDL where they could find the preferred agents in this therapeutic class.

**New Business:**

**Duplicate Atypical Antipsychotic Therapy in Pediatric Beneficiaries:**
At the February meeting the DUR Board asked HID to present data regarding duplicate therapy with multiple agents in this therapeutic class. Dr. Holeman presented a table noting the duration of duplicate therapy with more than one atypical antipsychotic for beneficiaries < 21 years old with the beneficiary count and percentage. A total of 7,308 beneficiaries < 21 years old received an atypical antipsychotic in 2009. Of these, 3.6% (262) were on duplicate therapy for 30 days, 2.3 %( 165) were on duplicate therapy for 60 days, 1.4 %( 105) received duplicate therapy for 90 days and 1% (74) were on duplicate therapy with two or more atypical antipsychotics for 120 days. The overall incidence of duplicate therapy appears to be minimal, based on these results. However, when considering the potential metabolic and extra pyramidal effects, in conjunction with expert opinions, the implementation of duplicate therapy edits may need to be considered.
**Recommendation:** HID recommended establishing edits at the point of sale that prohibit duplicate therapy with two or more atypical antipsychotics in pediatric beneficiaries. The edit would cause claims at the point of sale to deny when beneficiaries less than 18 years old receive more than one atypical antipsychotic within a specified time frame and can be overridden with a prior authorization request providing medical justification for requested therapy.
Dr. Donahoe questioned the support for duplicate therapy. Dr. Holeman stated that there was no support found for this duplication of therapy. It was the consensus of the Board to have HID present data at the next meeting on the usage of low-dose therapy of atypical antipsychotics. Dr. Donahoe motioned that duplicate therapy be denied at point of sale with the option of a prior authorization when medically justified by the prescriber. This motion was seconded by Dr. Strong. All voted in favor of the motion.
**Attention Deficit Hyperactivity Disorder: A Medicaid Prescribing Update**
The Board had requested that HID develop a Medicaid Prescribing Update that would outline recommendations from clinical guidelines regarding the proper evaluation and diagnosis of children for ADHD. The rationale provided for the development of such a document was to provide prescribers with a concise and accurate reference that could be used when evaluating children for possible ADHD, particularly those providers with little

or no formal training or education in the disorder. This update was presented to the Board for discussion and review. Dr. Donahoe suggested adding the Vanderbilt questionnaire to the back of this to facilitate the physician's review. HID will inquire about needed permission to add this document to the Medicaid Prescribing Update prior to the distribution by the Academic Detailers to the medical community. Dr. Holeman also noted that beginning 7/15/2010, Medicaid will implement quantity limits for the ADHD therapeutic class. This will require a physician to request an override through HID when prescribing more than the allowable quantity by Medicaid.

**Long-Acting Injectable Antipsychotic Use in Long-Term Care Settings**

Injectable antipsychotic formulations are divided into two groups: short-acting and long-acting. LTC beneficiaries are not required to have a prior authorization for the long-acting injectable antipsychotics, which is in contrast to the prior authorization requirement for these agents for all other beneficiaries. Dr. Holeman presented an analysis noting that there were 248 pharmacy claims for LTC residents totaling $132,926.91 for long-acting injectable antipsychotics. Long –acting injectable antipsychotic injections typically have been reserved for the most difficult patients where non-adherence to oral medication has been identified as a primary obstacle. Concerns have been raised over the need for long acting injectable antipsychotic medications in a LTC setting when beneficiaries live in a controlled environment where medication administration is supervised. The Board requested a cost comparison of oral antipsychotic therapy versus long-acting injectable antipsychotic therapy, to determine if shifting therapy to the oral agents would be a cost-efficient endeavor for Medicaid. The Board also requested a report identifying those beneficiaries receiving concurrent therapy with oral and long-acting injectable antipsychotic therapy, as well as the LTC facilities where the long-acting injectable antipsychotics are being used. These reports will be presented at the August meeting for further Board review before a decision is made to require prior authorizations for the long- acting injectable antipsychotics in LTC beneficiaries.

**The Role of Lipotropics in the Treatment of Cardiovascular Disease**

During the March 2010 Pharmacy and Therapeutics (P&T) meeting, there were discussions about non-statin lipotropics. Although the non-statin lipotropics have not been proven to reduce morbidity and mortality related to cardiovascular disease, prescribers often times use these agents based on data illustrating their LDL-lowering effects without regard to the lack of data for risk reduction of cardiovascular events. There seems to be a false sense of protection of the patient's wellbeing for both the prescriber and the patient. Based on this concern, the P&T Committee and DOM requested that the DUR Board review the utilization of this class to determine if the non-statin lipotropics are being used appropriately. The Committee also requested that the DUR Board determine what steps may be necessary to encourage appropriate use and improve outcomes for the Medicaid beneficiaries. The P&T Committee outlined two particular areas that should be addressed:

1. Are beneficiaries being given a trial of a statin prior to attempting treatment with a non-statin lipotropic?

*The ATPIII Final Report from the National Heart lung and Blood Institute supports the use of statins as first-line therapy for LDL-reduction based on results from 5 large clinical trials. These trials showed a documented decrease in cardiovascular disease and*

*total mortality as well as reductions in myocardial infarctions, revascularization procedures, stroke and peripheral vascular disease across all genders and ages with statin therapy. The P&T Committee agrees that statins should be the first line of treatment for beneficiaries with elevated cholesterol. Of the 1609 beneficiaries receiving non-statin lipotropics from 07/01/2009 – 12/31/2009, 518 (32%) received a statin in the prior 6 months. This indicates that a majority of beneficiaries were not given a trial of a statin prior to initiating therapy with the other lipotropics.*

2. Of those beneficiaries being treated with a non-statin lipotropic, how many have a hypertriglyceridemia diagnosis?

*According to the ATPIII Final Report, statins should be used as first-line treatment for LDL reduction in patients with hypertriglyceridemia, with the addition of nicotinic acid or fibrates for triglyceride reduction. In the absence of elevated LDL, the ATPIII Final Report does recommend the use of fibrates or nicotinic acid as first-line therapy to lower triglyceride levels. HID analyzed the data of the non-statin lipotropics to determine what percentage of utilization could be credited to a hypertriglyceridemia diagnosis. Only 35% of the beneficiaries receiving a non-statin lipotropic had a documented diagnosis of elevated triglycerides in the six-month period reviewed. Based on this data, it appears that the P&T Committee concerns are appropriate that the utilization of these agents cannot be attributed to a hypertriglyceridemia diagnosis.*

After Board discussion on the HID analysis the following recommendation was presented:

Dr. Donahoe recommended a point of sale denial for a non-statin lipotropic if pharmacy claims fail to indicate a trial of a statin in the last 6 months. This motion also included the allowance of approval for non-statin lipotropics in the presence of a hypertriglyceridemia diagnosis. Dr. Donahoe continued that this motion should exclude bile acid sequestrants which are commonly and appropriately used for other indications. This motion was seconded by Dr. Frank Wade and all voted in favor of the motion.

**ACEIs vs. ARBS: Appropriate Place in Treatment of Cardiovascular Disease**

At the April Pharmacy and Therapeutics Committee meeting, questions were raised regarding the relative efficacy of ACEIs and ARBs. Specifically, it was noted that current literature does not indicate that the more expensive ARBs are more beneficial than the cheaper ACEI in the treatment of hypertension and heart disease. Additionally, treatment guidelines such as the JNC7 report and the ACC/AHA Heart Failure guidelines both recommend ACEI as the primary therapy over ARBs. DOM asked HID to review the utilization data for these agents to determine what percentage of Medicaid beneficiaries received an ACEI before starting treatment with an ARB.

From 7/1/2009 thru 12/31/2009, 7,050 beneficiaries received an ARB through the Mississippi Medicaid pharmacy benefit program. Of these beneficiaries, 899 (13%) received an ACEI in the six months prior to this search. From this data, it appears that an overwhelming majority of the beneficiaries being treated with an ARB for hypertension and/or heart disease have not been managed based on current treatment guidelines and medical literature. The P&T Committee members recommended that Mississippi Medicaid require beneficiaries to attempt and fail treatment with an ACEI before starting therapy with an ARB. The P& T Committee asked that the DUR Board determine the necessary measures to promote appropriate use of ARBs in the Mississippi Medicaid

population. Dr. Paul Read made a motion to require a trial of an ACEI before granting approval of an ARB for Mississippi Medicaid beneficiaries. He also included in his motion to allow stable therapy for those beneficiaries currently being treated with an ARB. Dr. Donahoe seconded the motion and all voted in favor of this motion.

**Other Criteria Recommendations**

Dr. Reed asked for the Board to accept the proposed RDUR criteria recommendations as a block vote. All voted in favor of the motion

**FDA Updates:**

Dr. Holeman asked if there were any questions in regard to the submitted FDA updates. No questions were raised.

Dr. Reed called for the meeting to be adjourned at 3:35 p.m. The next meeting will be held at 2:00 p.m. on August 19, 2010.

Respectfully Submitted,
Health Information Designs, Inc.